

TDMS No. 20201 - 03
Test Type: 26-WEEK
Route: SKIN APPLICATION
Species/Strain: MICE/TG.AC HEMI

E09: SUMMARY OF DERMAL CLINICAL OBSERVATIONS AT SITE OF APPLICATION
TEF TRANSGENICS (PECDF)
CAS Number: 57117-31-4

Date Report Reqsted: 06/14/2006
Time Report Reqsted: 15:27:08
First Dose M/F: NA / 04/21/03
Lab: BAT

C Number: C20201C
Lock Date: 07/24/2004
Cage Range: ALL
Date Range: ALL
Reasons For Removal: ALL
Removal Date Range: ALL
Treatment Groups: Include ALL

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 Lab: BAT

SEX: FEMALE		WEEK: 27						
OBSERVATION	0 NG/KG		72 NG/KG		242 NG/KG		720 NG/KG	
	NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED	
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
Irritation	0 / 0	1 / 20 DAY 178 10/15/03	0 / 0	8 / 20 DAY 58 06/17/03	0 / 0	11 / 20 DAY 51 06/10/03	0 / 0	11 / 20 DAY 44 06/03/03
Mass Small (1mm-5mm)	0 / 0	2 / 20 DAY 143 09/10/03	0 / 0	15 / 20 DAY 72 07/01/03	0 / 0	18 / 20 DAY 37 05/27/03	0 / 0	20 / 20 DAY 37 05/27/03
Mass Large (16mm and Larger)							0 / 0	1 / 20 DAY 157 09/24/03
Mass 1	0 / 0	2 / 20 DAY 143 09/10/03	0 / 0	13 / 20 DAY 79 07/08/03	0 / 0	15 / 20 DAY 37 05/27/03	0 / 0	14 / 20 DAY 37 05/27/03
Mass 2			0 / 0	3 / 20 DAY 72 07/01/03	0 / 0	6 / 20 DAY 51 06/10/03	0 / 0	7 / 20 DAY 44 06/03/03
Mass 3			0 / 0	2 / 20 DAY 122 08/20/03	0 / 0	1 / 20 DAY 72 07/01/03	0 / 0	4 / 20 DAY 44 06/03/03
Mass 4					0 / 0	2 / 20 DAY 101 07/30/03	0 / 0	2 / 20 DAY 51 06/10/03
Mass 5							0 / 0	2 / 20 DAY 79 07/08/03

* ANIMALS WITH OBSERVATION IN CURRENT PERIOD / TOTAL ANIMALS OBSERVED IN CURRENT PERIOD (WITHIN 7 DAYS OF RUN DATE)
 + ROW 1 = CUMULATIVE NO. OF ANIMALS WITH OBSERVATION / TOTAL ANIMALS STARTED ON STUDY
 ROW 2 = DAY OF ONSET

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 Lab: BAT

SEX: FEMALE		WEEK: 27	
OBSERVATION	1520 NG/KG		
	NUMBER OBSERVED		
	CURRENT*	TOTAL+	
Irritation	0 / 0	13 / 20 DAY 44 06/03/03	
Mass Small (1mm-5mm)	0 / 0	20 / 20 DAY 37 05/27/03	
Mass Large (16mm and Larger)	0 / 0	2 / 20 DAY 157 09/24/03	
Mass 1	0 / 0	10 / 20 DAY 37 05/27/03	
Mass 2	0 / 0	9 / 20 DAY 37 05/27/03	
Mass 3	0 / 0	2 / 20 DAY 51 06/10/03	
Mass 4	0 / 0	3 / 20 DAY 58 06/17/03	
Mass 5	0 / 0	2 / 20 DAY 58 06/17/03	

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	NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED		
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL	
Mass 6							0 / 0	4 / 20 DAY 51 06/10/03	
Mass 7									
Mass 8									
Papilloma Small (1mm-5mm)			0 / 0	12 / 20 DAY 86 07/15/03	0 / 0	17 / 20 DAY 51 06/10/03	0 / 0	20 / 20 DAY 51 06/10/03	
Papilloma Medium (6mm-15mm)	0 / 0	1 / 20 DAY 157 09/24/03	0 / 0	8 / 20 DAY 101 07/30/03	0 / 0	14 / 20 DAY 79 07/08/03	0 / 0	16 / 20 DAY 79 07/08/03	
Papilloma Large (16mm and Larger)					0 / 0	1 / 20 DAY 129 08/27/03	0 / 0	2 / 20 DAY 129 08/27/03	
Papilloma ¹ 1	0 / 0	1 / 20 DAY 157 09/24/03	0 / 0	10 / 20 DAY 94 07/23/03	0 / 0	10 / 20 DAY 51 06/10/03	0 / 0	5 / 20 DAY 51 06/10/03	
Papilloma ¹ 2			0 / 0	7 / 20 DAY 122 08/20/03	0 / 0	12 / 20 DAY 58 06/17/03	0 / 0	5 / 20 DAY 58 06/17/03	

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ROW 2 = DAY OF ONSET

¹ NUMBER UNDER PAPILLOMA INDICATES THE COUNT OF PAPILLOMAS PER ANIMAL FOR THAT WEEK ON DOSE

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SEX: FEMALE		WEEK: 27	
OBSERVATION	1520 NG/KG		
	NUMBER OBSERVED		
	CURRENT*	TOTAL+	
Mass 6			
Mass 7	0 / 0	3 / 20 DAY 58 06/17/03	
Mass 8	0 / 0	1 / 20 DAY 86 07/15/03	
Papilloma Small (1mm-5mm)	0 / 0	20 / 20 DAY 51 06/10/03	
Papilloma Medium (6mm-15mm)	0 / 0	18 / 20 DAY 115 08/13/03	
Papilloma Large (16mm and Larger)	0 / 0	2 / 20 DAY 136 09/03/03	
Papilloma ¹ 1	0 / 0	2 / 20 DAY 58 06/17/03	
Papilloma ¹ 2	0 / 0	4 / 20 DAY 51 06/10/03	

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 Lab: BAT

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OBSERVATION	0 NG/KG		72 NG/KG		242 NG/KG		720 NG/KG	
	NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED	
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
Papilloma ¹ 3			0 / 0	6 / 20 DAY 86 07/15/03	0 / 0	7 / 20 DAY 86 07/15/03	0 / 0	10 / 20 DAY 51 06/10/03
Papilloma ¹ 4			0 / 0	4 / 20 DAY 129 08/27/03	0 / 0	11 / 20 DAY 79 07/08/03	0 / 0	7 / 20 DAY 51 06/10/03
Papilloma ¹ 5			0 / 0	2 / 20 DAY 143 09/10/03	0 / 0	8 / 20 DAY 94 07/23/03	0 / 0	4 / 20 DAY 65 06/24/03
Papilloma ¹ 6			0 / 0	4 / 20 DAY 136 09/03/03	0 / 0	12 / 20 DAY 108 08/06/03	0 / 0	8 / 20 DAY 58 06/17/03
Papilloma ¹ 7			0 / 0	2 / 20 DAY 164 10/01/03	0 / 0	7 / 20 DAY 122 08/20/03	0 / 0	4 / 20 DAY 72 07/01/03
Papilloma ¹ 8			0 / 0	1 / 20 DAY 150 09/17/03	0 / 0	6 / 20 DAY 129 08/27/03	0 / 0	6 / 20 DAY 58 06/17/03
Papilloma ¹ 9			0 / 0	2 / 20 DAY 164 10/01/03	0 / 0	8 / 20 DAY 129 08/27/03	0 / 0	3 / 20 DAY 94 07/23/03
Papilloma ¹ 10					0 / 0	9 / 20 DAY 136 09/03/03	0 / 0	8 / 20 DAY 65 06/24/03

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OBSERVATION	1520 NG/KG		
	NUMBER OBSERVED		
	CURRENT*	TOTAL+	
Papilloma ¹ 3	0 / 0	6 / 20 DAY 51 06/10/03	
Papilloma ¹ 4	0 / 0	7 / 20 DAY 58 06/17/03	
Papilloma ¹ 5	0 / 0	4 / 20 DAY 58 06/17/03	
Papilloma ¹ 6	0 / 0	6 / 20 DAY 65 06/24/03	
Papilloma ¹ 7	0 / 0	6 / 20 DAY 65 06/24/03	
Papilloma ¹ 8	0 / 0	7 / 20 DAY 72 07/01/03	
Papilloma ¹ 9	0 / 0	6 / 20 DAY 65 06/24/03	
Papilloma ¹ 10	0 / 0	4 / 20 DAY 65 06/24/03	

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	NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED	
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
Papilloma ¹ 11					0 / 0	4 / 20 DAY 129 08/27/03	0 / 0	6 / 20 DAY 79 07/08/03
Papilloma ¹ 12			0 / 0	1 / 20 DAY 171 10/08/03	0 / 0	2 / 20 DAY 164 10/01/03	0 / 0	5 / 20 DAY 65 06/24/03
Papilloma ¹ 13					0 / 0	2 / 20 DAY 150 09/17/03	0 / 0	6 / 20 DAY 86 07/15/03
Papilloma ¹ 14					0 / 0	5 / 20 DAY 157 09/24/03	0 / 0	7 / 20 DAY 94 07/23/03
Papilloma ¹ 15			0 / 0	1 / 20 DAY 178 10/15/03	0 / 0	1 / 20 DAY 185 10/22/03	0 / 0	5 / 20 DAY 79 07/08/03
Papilloma ¹ 16					0 / 0	2 / 20 DAY 178 10/15/03	0 / 0	5 / 20 DAY 72 07/01/03
Papilloma ¹ 17					0 / 0	4 / 20 DAY 171 10/08/03	0 / 0	7 / 20 DAY 108 08/06/03
Papilloma ¹ 18					0 / 0	1 / 20 DAY 187 10/24/03	0 / 0	5 / 20 DAY 86 07/15/03

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OBSERVATION	1520 NG/KG		
	NUMBER OBSERVED		
	CURRENT*	TOTAL+	
Papilloma ¹ 11	0 / 0	8 / 20 DAY 72 07/01/03	
Papilloma ¹ 12	0 / 0	3 / 20 DAY 72 07/01/03	
Papilloma ¹ 13	0 / 0	5 / 20 DAY 72 07/01/03	
Papilloma ¹ 14	0 / 0	5 / 20 DAY 79 07/08/03	
Papilloma ¹ 15	0 / 0	8 / 20 DAY 79 07/08/03	
Papilloma ¹ 16	0 / 0	7 / 20 DAY 86 07/15/03	
Papilloma ¹ 17	0 / 0	6 / 20 DAY 86 07/15/03	
Papilloma ¹ 18	0 / 0	3 / 20 DAY 79 07/08/03	

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	NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED		NUMBER OBSERVED	
	CURRENT*	TOTAL+	CURRENT	TOTAL	CURRENT	TOTAL	CURRENT	TOTAL
Papilloma ¹ 19			0 / 0	1 / 20 DAY 186 10/23/03	0 / 0	2 / 20 DAY 164 10/01/03	0 / 0	2 / 20 DAY 101 07/30/03
Papilloma ¹ 20					0 / 0	4 / 20 DAY 171 10/08/03	0 / 0	15 / 20 DAY 79 07/08/03
Ulcer					0 / 0	2 / 20 DAY 115 08/13/03	0 / 0	4 / 20 DAY 101 07/30/03

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OBSERVATION	1520 NG/KG		
	NUMBER OBSERVED		
	CURRENT*	TOTAL+	
Papilloma ¹ 19	0 / 0	2 / 20 DAY 79 07/08/03	
Papilloma ¹ 20	0 / 0	19 / 20 DAY 86 07/15/03	
Ulcer	0 / 0	10 / 20 DAY 86 07/15/03	

*** END OF REPORT ***

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